

**Community Development and Nutrition Education in Banke District, Nepal: Effect on
Child Health and Growth**

Today's date: April 20, 2018

Date of approval by Tufts IRB: October 2, 2014

Statistical Analysis Plan

Statistical analysis plan

Consultant biostatisticians from the Friedman School of Nutrition, Tufts University, Boston, USA, has provided a detailed analysis and overview of the study design. Several series of calculations and power analyses were conducted to determine the needed sample size to demonstrate a difference of 0.25 Z scores over the study period. Depending on the exact outcome variable measured, the sample size will need to be at least 600 children total in the target age range (including all 3 groups); we are requesting permission to enroll as many as 2000. Larger sample sizes are more desirable, as this will greatly strengthen the analyses given the number of variables to consider. Methods to account for variables within each family, including SES, gender, birth order, etc. are also being developed. These sub-analyses will likely yield information of great interest, such as the characteristics of families whose children do best after Heifer activities. This information could be used by Heifer to optimize the impact of its activities. Graphs, histograms, and summary statistics will be used to describe baseline measurements of each analytic variable. Data will similarly be summarized at each of the serial measurements. Preliminary analyses will compare pre and post-intervention measurements for changes in anthropometric measurements, health appraisal, diet, quality of life, and family socio-economic status. Because of the expected clustering within household, hierarchical regression models will be used to obtain robust estimates of the variance, as well as repeated measurements over time. These models can also incorporate seasonal and secular trends as well as changes in the intervention implementation over time. Interaction terms in these models will be used to explore for any differential impact of the intervention components relating to individual or household characteristics (e.g. gender of child). An interim review of project results, specifically the findings related to child growth and health, will be performed after the 12 month assessment. The project Executive Committee will carefully review these outcomes and recommend any needed inputs to the Control Group communities, including the possible termination of the research investigation and introduction of *Heifer* activities. The Data Manager, based in Nepal, will have overall responsibility for the security and accessibility of the study database. All directories and databases will be password-protected, all data forms will be kept in secure files, no individual subject identifiers will be included in the analytic database, and access to the data directories will follow the policy of least privilege where each user's access will be restricted to the minimum necessary. Data will be entered using CSPro software; discrepancies and outliers will be resolved by review of the data collection forms.